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medical technology

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JAN 2 4 2011

K10 2218

510(k) Summary in accordance with 21 CFR 807.92

Device Name:	Compact Piezo P2K Powercare
Type of 510(k) submission:	Traditional
Date of Submission:	4 August 2010
Manufacturer:	Mectron Spa Via Loreto, 15, Carasco, GE 16042, Italy
FDA Registration Number:	3003933619
510(k) Owner:	Mectron Spa Via Loreto, 15, Carasco, GE 16042, Italy
510(k) Contact:	Roger Gray VP, Quality and Regulatory Donawa Lifescience Consulting Piazza Albania, 10, 00153 Rome, Italy Tel: +39 06 578 2665 Fax: +39 06 574 3786
Trade name:	Compact Piezo P2K Powercare
Common Name:	Ultrasonic scaler
Class:	Class II
Product Code:	ELC
Classification Regulation:	21 CFR 872.4850: Ultrasonic scaler
Predicate devices:	Piezosurgery 3 (K091227) and SP Newtron Module (K033764)

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Device Description:

The Compact Piezo P2K and Powercare are multipurpose piezoelectric ultrasonic scaler sub-assembly devices intended to be incorporated into a dental unit/table-top device and used for ultrasonic treatment in scaling, periodontics, endodontics and prosthetics dental applications.

The Compact Piezo P2K and Powercare devices are intended to be supplied as modular sub-assemblies devices to OEM manufacturers of dental units.

The subject devices consist of an ultrasonic generator, a handpiece with cord, a range of insert tips, a torque wrench and a wiring connections kit.

The subject devices are intended to be assembled inside a dental unit and connected to the unit's electrical supply by the wiring connections kit provided.

The handpiece cord is connected directly to the ultrasonic generator from which it receives the functional drive signals, including those for water supply from the dental unit for water irrigation. The ultrasonic power and water flow are simultaneously activated by pressing the footswitch of the dental unit. The power output and water flow are adjusted by the dental unit's controls.

The Compact Piezo P2K and the Power Care devices use a piezoelectric transducer inside the handpiece to generate the insert tip oscillation. The ultrasonic transducer uses four piezoceramic disks to convert the generator's electrical signal to ultrasonic mechanical vibration of the insert tip.

A key function of the ultrasonic generator is to locate the optimal frequency of resonance of the transducer/insert tip and then to drive the output at this resonant frequency.

Indications for Use: The Compact Piezo P2K and Powercare devices are ultrasonic scalers intended for use, with the appropriate associated insert tips, in the following dental applications:

Scaling:
All general procedures for removal of supragingival and interdental calculus7plaque deposits.
Periodontology:
Periodontal therapy and debridement for all types of periodontal diseases, including periodontal pocket irrigation and cleaning.
Endodontics:
All treatments for root canal reaming, irrigation, revision, filling, gutta-percha condensation and retrograde preparation.
Restorative and Prosthetics:
Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

Non-clinical testing:
Non-clinical testing of the device components covered by this 510(k) submission includes:

- Testing to confirm compliance with the safety requirements of standard IEC 60601-1
- Testing to confirm compliance with the EMC requirements of standard IEC 60601-1-2
- Each tip design is tested to ensure that the desired vibrational mode occurs at a frequency within the specified range for the device

Technological Characteristics and Substantial Equivalence:
The Compact PiezoP2K and Powercare are substantially equivalent to the predicate devices Piesurgery 3, cleared under 510(k) reference K091227, and SP Newtron Module, cleared under 510(k) reference K033764.

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The subject devices and the predicate devices use same piezoelectric ultrasonic technology to generate the mechanical micro-vibration of the insert tips for the ultrasound treatments.

Both the subject devices, and the predicate device SP Newtron Module are ultrasonic scalers (product code ELC) intended for use in the following dental applications

- Scaling treatments
- Periodontal treatments
- Endodontics treatments
- Restorative/Conservative treatments.

Predicate device Piezosurgery 3 (product codes DZI, ELC), is cleared by FDA for all the same dental applications as claimed above for the subject devices except for the restorative/conservative treatments.

The Compact Piezo P2K and Powercare devices comply with the electrical safety and electromagnetic compatibility requirements established by the standards IEC 60601-1 and IEC 60601-1-2.

Conclusion

The Compact Piezo P2k and the Powercare and the predicate devices share the same general intended use and technology.

The differences that exist between the subject devices and the predicate devices relating to technical specifications, performance and intended use are minor and do not affect the safety and effectiveness of the Compact Piezo P2K and Powercare.

Therefore the data presented in this submission demonstrates the similarities in the intended use/indications of use and technology between the Compact Piezo P2K, Powercare and the predicate devices, the Piezosurgery 3 and SP Newtron Module, and thus supports a finding of substantial equivalence between the subject devices and the referenced predicate devices which are already in commercial distribution in the United States.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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C/O Mr. Roger Gray
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JAN 24 2011

Re: K102218
Trade/Device Name: Compact Piezo P2K and Powercare Devices
Regulation Number: 21 CFR 872.4850
Regulation Name: Ultrasonic Scaler
Regulatory Class: II
Product Code: ELC
Dated: January 13, 2011
Received: January 18, 2011

Dear Mr. Gray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102218

Indications for Use Statement

Indications for Use

510(k) Number (if known): Not known

Device Name: Compact Piezo P2K and Powercare devices

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Restorative and Prosthetics:
Cavity preparation, removal of prostheses, amalgam condensation, finishing of crown preparations and inlay/onlay condensation.

Prescription Use (Part 21 CFR 801 Subpart D)	☒	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	☐

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

RS Berzins for Dr. S. Runner

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102218